Electro *Kinetic* Technologies
Ergonomic Solutions for Transport

K111095

AUG - 3 2011

Section 5-510(k) Summary

Date Prepared: July 23, 2011

Submitter: Electro Kinetic Technologies, LLC
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Germantown, Wisconsin 53022

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Trade Name of Device: BREEZ 1025 Electric Transport Chair

Classification: Wheelchair, Powered Wheelchair – 21 CFR 890.3860

Class: Class II

Product Code: ITI

Predicate Device: Heartway Attendant-Controlled Power Chair, TC1 (K071006)

Intended Use
The BREEZ Electric Transport Chair is intended to transport patients within acute, alternative and long term care facilities. The device can be operated indoors on carpeting, linoleum and other floors, and on sidewalks. The BREEZ Electric Transport Chair is controlled, steered and operated completely by a trained caregiver.

Device Description
The BREEZ Electric Transport Chair is a motorized device that allows caregivers to move patients up to 750 pounds in weight.

The device has self-contained batteries to provide power that can be recharged by an on-board battery charger that can be plugged into a 120/240 VAC outlet when the device is not in use. The device is supported by four wheels whereby the front wheels provide the motive force to propel the unit in either the forward or reverse direction. The caregiver directs the movement of the device using a steering handlebar and various hand-operated controls attached to the rear of the device.

Functional & Safety Testing
The BREEZ Electric Transport Chair was tested in accordance with the following voluntary standards.

CISPR 11 (Radiated/Conducted Emissions)

EN61000-4-2: 2008-10 Electrostatic Discharge

EN61000-4-3: 2008-4 Radiated Immunity Test

As required by FDA's July 26, 1995, draft publication entitled "Guidance Document for the preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles", dimensional, performance, and static tests were conducted according to RESNA WC-1: 2009 and RESNA WC-2: 2009.

In all instances, the BREEZ Electric Transport Chair met the required performance criteria and functioned as intended.

The seat material used on the BREEZ Electric Transport Chair conforms to the California Flammability Regulation (Bulletin 117, Section E).

Substantial Equivalence

The BREEZ Electric Transport Chair is substantially equivalent to the Heartway Attendant-Controlled Power Chair, TC1.

This device has the same intended use as the legally marketed device as shown in the substantial equivalence table, with technological characteristics that do not raise questions on the safety and effectiveness during use. Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any questions as to the safety and effectiveness, therefore the BREEZ Electric Transport Chair is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Electro Kinetic Technologies, LLC
% Mr. Raymond Erbe
President
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Germantown, Wisconsin 53022

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Re: K111095
Trade/Device Name: Breez Electric Transport Chair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: July 25, 2011
Received: July 28, 2011

Dear Mr. Erbe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111095

Device Name: BREEZ ELECTRIC TRANSPORT CHAIR

Indications For Use:

The BREEZ Electric Transport Chair is intended to transport patients within acute, alternative and long term care facilities. The device can be operated indoors on carpeting, linoleum and other floors, and on sidewalks. The BREEZ Electric Transport Chair is controlled, steered and operated completely by a trained caregiver.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111095